IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INGENUS PHARMACEUTICALS, LLC, Plaintiff, v. HETERO USA, INC., HETERO LABS LTD., and HETERO LABS LTD. UNIT-VI, Defendants.	C.A. No. 24-1025-JLH

PLAINTIFF'S ANSWER TO HETERO'S COUNTERCLAIMS AND FIRST AMENDED AFFIRMATIVE DEFENSES

Plaintiff Ingenus Pharmaceuticals, LLC ("Ingenus" or "Counterclaim Defendant"), hereby responds to the Counterclaims and First Amended Affirmative Defenses of Defendants/Counterclaim-Plaintiffs Hetero USA, Inc., Hetero Labs Ltd., and Hetero Labs Ltd. Unit-VI (collectively, "Hetero" or "Defendants"), as follows. Plaintiff denies every allegation contained in Defendants' Counterclaims that is not expressly admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications or speculations that arguably follow from the admitted facts. Plaintiff denies that Defendants are entitled to the relief requested in the Counterclaims or to any other relief.

Plaintiff further denies that Defendants are entitled to relief under any affirmative defenses.

HETERO'S COUNTERCLAIM

For its counterclaims against Counterclaim-Defendant Ingenus Pharmaceuticals, LLC ("Ingenus" or "Counterclaim-Defendant"), Counterclaim-Plaintiff Hetero USA, Inc., Hetero Labs Ltd. Unit-V, and Hetero Labs Ltd. (collectively, "Hetero" or "Counterclaim-Plaintiffs"), state as follows:

ANSWER. The foregoing preamble states one or more legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies the allegations.

THE PARTIES

1. On information and belief, Ingenus is a corporation organized and existing under the laws of the state of Florida having its principal place of business at 4190 Millenia Blvd., Orlando, Florida 32839.

ANSWER. Plaintiff admits the allegations of Paragraph 1.

2. Counterclaim-Plaintiff Hetero Labs Limited is a corporation organized and existing under the laws of India, having a principal place of business at Floor 9-11, Tower 30, RMZ Nexity Sy. No. 83/1, Knowledge City, Raidurg, Hyderabad – 500081, Telangana, India.

ANSWER. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 2 of the Counterclaim, and on that basis denies the same.

3. Counterclaim-Plaintiff Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854

ANSWER. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 3 of the Counterclaim. However, Plaintiff alleged these same facts on information and belief in the Complaint (D.I. 1 at 2, ¶ 3), which Defendants have admitted (D.I. 12 at 2, ¶ 3).

NATURE OF THE ACTION

4. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*., that United States Patent No. 10,993,952 ("the '952 patent" or the "Patent-In-Suit") is invalid and/or not infringed.

ANSWER. The allegations in Paragraph 4 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies the allegations.

JURISDICTION AND VENUE

5. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

ANSWER. The allegations in Paragraph 5 of the Counterclaim set forth legal conclusions to which no response is required. However, Plaintiff does not contest subject matter jurisdiction over the present Counterclaim.

6. This Court has personal jurisdiction over Ingenus because, among other reasons, Ingenus subjected itself to the jurisdiction of this Court by filing its complaint here.

ANSWER. The allegations in Paragraph 6 of the Counterclaim set forth legal conclusions to which no response is required. However, Plaintiff does not contest personal jurisdiction for this action only.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiff's choice of forum

ANSWER. The allegations in Paragraph 7 of the Counterclaim set forth legal conclusions to which no response is required. However, Plaintiff does not contest venue for this action only.

8. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patent-in-Suit.

ANSWER. The allegations in Paragraph 8 of the Counterclaim set forth legal conclusions to which no response is required. However, Plaintiff does not contest that

there is an actual and justiciable controversy between the parties as to the infringement by Defendants of the Patent-in-Suit for this action only.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

9. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq*., as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

ANSWER. The allegations in Paragraph 9 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 9 of the Counterclaim, and on that basis, denies the same.

10. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. See 21 U.S.C. § 355.

ANSWER. The allegations in Paragraph 10 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 10 of the Counterclaim, and on that basis, denies the same.

11. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. See 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

ANSWER. - The allegations in Paragraph 11 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required,

Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 11 of the Counterclaim, and on that basis, denies the same.

12. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

ANSWER. The allegations in Paragraph 12 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 12 of the Counterclaim, and on that basis, denies the same.

13. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. See 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

ANSWER. The allegations in Paragraph 13 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 13 of the Counterclaim, and on that basis, denies the same.

B. FDA Approval of New Generic Drugs

14. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. See Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

ANSWER. The allegations in Paragraph 14 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required,

Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 14 of the Counterclaim, and on that basis, denies the same.

15. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

ANSWER. The allegations in Paragraph 15 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 15 of the Counterclaim, and on that basis, denies the same.

16. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. See 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

ANSWER. The allegations in Paragraph 16 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 16 of the Counterclaim, and on that basis, denies the same.

17. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. See 21 U.S.C. § 355(j)(2)(A)(vii)(IV); see also 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

ANSWER. The allegations in Paragraph 17 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 17 of the Counterclaim, and on that basis, denies the same.

18. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. See 21 U.S.C. § 355(j)(2)(B).

ANSWER. The allegations in Paragraph 18 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 18 of the Counterclaim, and on that basis, denies the same.

19. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. See 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

ANSWER. The allegations in Paragraph 19 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 19 of the Counterclaim, and on that basis, denies the same.

20. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. See 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER. The allegations in Paragraph 20 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 20 of the Counterclaim, and on that basis, denies the same.

21. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id*. If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id*.

ANSWER. The allegations in Paragraph 21 of the Counterclaim set forth legal conclusions to which no response is required. To the extent a response is required, Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 21 of the Counterclaim, and on that basis, denies the same.

C. Hetero's ANDA and Plaintiff' Complaint

22. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 219271 ("Hetero's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic Cyclophosphamide Solution ("Hetero's ANDA Product").

ANSWER. Plaintiff admits that Hetero is the owner of ANDA No., 219271, seeking approval of that ANDA to engage in the commercial use, sale, and/or distribution of Cyclophosphamide solution described therein. Plaintiff denies the other allegations in Paragraph 22 of the Counterclaim.

23. On information and belief, Ingenus holds approved New Drug Application ("NDA") No. 212501 for Cyclophosphamide Solution under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

ANSWER. Plaintiff admits that Ingenus is the holder of New Drug Application (NDA) No. 212501 which was approved by the Food and Drug Administration ("FDA") for the sale and manufacture of Cyclophosphamide for intravenous use ("NDA Product"). Plaintiff denies the other allegations in Paragraph 23 of the Counterclaim.

24. Hetero's ANDA shows that Hetero's ANDA Products are bioequivalent to the products that are the subject of NDA No. 212501.

ANSWER. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 24 of the Counterclaim, and on that basis, denies the same.

25. On information and belief, Ingenus caused the '952 patent to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as a patent that purportedly claims the drug listed in, and/or purportedly claim a method of using the drug for which Ingenus submitted, NDA No. 212501.

ANSWER. Plaintiff admits that Ingenus submitted the '952 Patent for listing in the electronic version of the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book) in connection with Cyclophosphamide Injection. Plaintiff denies the other allegations in Paragraph 25 of the Counterclaim.

26. The '952 patent is entitled "Stable Ready to Use Cyclophosphamide Liquid Formulations" and the issue date identified on the cover of the '952 patent is May 4, 2021.

ANSWER. Plaintiff admits that the U.S. Patent and Trademark Office issued U.S. Patent No. 10,993,952 (the '952 Patent) on May 4, 2021, and that the '952 Patent is entitled "STABLE READY TO USE CYCLOPHOSPHAMIDE LIQUID FORMULATIONS." Plaintiff denies the other allegations in Paragraph 26 of the Counterclaim.

27. Hetero's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '952 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

ANSWER. Plaintiff lacks knowledge and information sufficient to form a belief as to the truth of the matters alleged in Paragraph 27 of the Counterclaim, and on that basis denies the same.

28. On July 31, 2024, Hetero sent Plaintiff written notice of Hetero's Paragraph IV Certifications ("Hetero's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Notice Letter asserted that the claims of the '952 patent are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

ANSWER. Plaintiff is unable to respond to Paragraph 28 of the Counterclaim due to confidentiality obligations and therefore denies the same.

29. Hetero's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

ANSWER. Plaintiff is unable to respond to Paragraph 29 of the Counterclaim due to confidentiality obligations and therefore denies the same

30. On September 11, 2024, Plaintiff filed the present lawsuit alleging infringement of the '952 patent. There has been and now is an actual and justiciable controversy between Hetero and Plaintiff as to whether Hetero's ANDA Product infringes, induces infringement, or contributes to the infringement of any valid and enforceable claim of the '952 patent.

ANSWER. Plaintiff admits that the instant action, titled Complaint for Patent Infringement, was filed on September 11, 2024. Plaintiff incorporates by reference the answer set forth in Paragraph 8. Plaintiff denies the remaining allegations in Paragraph 30 of the Counterclaim.

COUNT I
Declaratory Judgment of Non-Infringement of the '952 Patent

31. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

ANSWER. Plaintiff incorporates by reference the answers set forth in Paragraphs 1-30.

32. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '952 patent.

ANSWER. Paragraph 32 states legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies, generally and specifically, the allegations in Paragraph 32.

33. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the '952 patent is not infringed by Hetero's ANDA or the products or activities described therein.

ANSWER. Plaintiff is unable to respond to Paragraph 33 of the Counterclaim due to confidentiality obligations and therefore denies the same

34. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '952 patent and is not liable for such infringement.

ANSWER. Paragraph 34 states legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies, generally and specifically, the allegations in Paragraph 34.

COUNT II
Declaratory Judgment of Invalidity of the '952 Patent

35. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

ANSWER. Plaintiff incorporates by reference the answers set forth in Paragraphs 1-34.

36. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Hetero regarding whether the claims of the '952 patent are invalid.

ANSWER. Paragraph 36 states legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies, generally and specifically, the allegations in Paragraph 36.

37. Hetero incorporates by reference Hetero's Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '952 patent are invalid.

ANSWER. Plaintiff is unable to respond to Paragraph 37 of the Counterclaim due to confidentiality obligations and therefore denies the same

38. Hetero is entitled to a declaration that all claims of the '952 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

ANSWER. Paragraph 38 states legal conclusions to which no response is required. To the extent a response is required, Plaintiff denies, generally and specifically, the allegations in Paragraph 38.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests the following relief:

A. Dismiss the Counterclaim of Hetero with prejudice;

B. Enter judgment in favor of Plaintiff Ingenus, and against Defendant Hetero, in accordance with Plaintiff's complaint;

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval of Defendant's ANDA shall be no earlier than the last expiration date of the '952 patent, or any later expiration of exclusivity for the '952 patent, including any extensions or regulatory exclusivities;

D. Entry of a permanent injunction enjoining Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf from commercially manufacturing, using, offering for sale, or selling the ANDA Products within the United States, or importing the ANDA Products into the United States, until the expiration of the '952 patent;

E. A declaration under 28 U.S.C. § 2201 that if Defendant, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with Defendant or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of the ANDA Product, it will constitute an act of infringement pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

F. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendant engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, or any product that infringes the '952 patent, or induces or contributes to such conduct, prior to the expiration of the '952 patent;

G. An order staying Hetero's ANDA for a 30-month time period referred to within 21 U.S.C. § 355(j)(5)(B)(iii);

H. A finding that this is an exceptional case, and an award of attorneys' fees and costs to Plaintiff in this action pursuant to 35 U.S.C. § 285; and

I. Such other and further relief as the Court deems just and proper.

Dated: July 9, 2025

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